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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/441,493      | 11/17/1999  | JAMES MARTIN LENHARD | PU3571US            | 4399             |

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EXAMINER

ZEMAN, ROBERT A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 01/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/441,493

Applicant(s)

LENHARD ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8 and 13-24 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-15-02 has been entered.

The amendment filed on 12-17-2002 is acknowledged. Claims 13 and 14 have been amended. Claims 17-24 have been added. Claims 9-12 have been canceled. Claims 1-8 and 13-24 are pending. Claims 1-8 remain withdrawn from consideration since they are drawn to non-elected inventions. Claims 13-24 are currently under examination.

### ***Drawings***

Applicant is required to submit corrected drawings in reply to this Office action. The requirement for corrected drawings will not be held in abeyance. Failure to timely submit the proposed drawing correction will result in the abandonment of the application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-17 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of determining the temperature of (or the change in relative temperature in) internal tissues or organs comprising replacing a portion of skin sufficient to expose the internal organ or tissue with a infrared-invisible polymer and measuring said temperature using infrared thermography in **mice or rats**, does not reasonably provide enablement for methods of determining the temperature of (or the change in relative temperature in) internal tissues or organs comprising replacing a portion of skin sufficient to expose the internal organ or tissue with a infrared-invisible polymer and measuring said temperature using infrared thermography **in any other mammal other than mice or rats**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification provides examples of mice and rats having portions of their skin removed (peeled back) and replaced with an infrared-invisible polymer (see page 35, Example 22, Figure 26 and Figures 28-30). However, the specification provides no guidance as the area of skin that must be replaced relative to the size of the mammal, whether said area is dependent on the physical characteristics (i.e. size, percent body fat, presence of fur, etc.) of the mammal or the effect of bone, cartilage and muscle mass on infrared thermography. Additionally, the specification is silent on the effect adipose tissue; cartilage, muscle and bone have on the required “exposing” of the tissue or internal organ. Therefore, due to the lack of guidance within the specification, one of skill in the art would not be able to use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is rendered vague and indefinite by the use of the phrase “portion of skin sufficient to expose the internal organ”. It is unclear what is meant by said phrase. What constitutes “exposure”? How much skin must be removed in order to “expose” an internal organ such as the heart or lung that is encased in layers of muscle, bone and cartilage? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 15 is rendered vague and indefinite by the use of the phrase “wherein one or more dosages of said test agent are sequentially administered and the temperature of the organ for each dose **in** determined”. Are the temperature determinations made before or after the administration of each dose? Are single doses given sequentially or multiple doses? Is said method limited to organs? Additionally, it should be noted that the rejected claim contains an obvious typographical error. The word “in” should read, “is”. As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 19 is rendered vague and indefinite by the use of the terms “relative temperature” and “relative temperature changes”. It is unclear what is meant by said term. The temperature “relative” to what? What constitutes the baseline? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claims 19-22 are rendered vague and indefinite by the use of the phrase “removing the mammalian skin overlaying the internal tissue or organ”. It is unclear what is meant by said

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phrase. What portion of skin is removed? What constitutes “overlying” an internal organ or tissue? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 21 is rendered vague and indefinite by the use of the phrase “the relative temperature change of the tissue or organ for each dose is monitored”. It is unclear what is meant by the term “monitored”. What steps are involved in “monitoring”? What time points are used? Does one “monitor” said temperature change prior to or after the administration of each dose?

Claim 21 is rendered vague and indefinite by the use of the phrase “one or more doses of the test agent are administered”. It is unclear whether the multiple doses are administered simultaneously or over time.

### ***Conclusion***

No claim is allowed.

Claims 13-24 are free of the art of record since no other method of infrared thermography includes the step of replacing a portion of skin with an infrared-invisible polymer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 608-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

Robert A. Zeman  
January 15, 2003